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Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fischer-s Lane; Room 1061
Rockville, Maryland 20852
Docket #: 97N-484S

RE: Proposal to regulate allograft tissue

I express my very sincere concerns vis-a-vis a proposed regulation that appeared in the September 30, 1999, issue of the Federal Register vis-a-vis regulation of allograft materials as medical devices.

At the present time, the use of bone allografts and other musculoskeletal allografts works extremely well vis-a-vis the safety issues of which the FDA regulates. I do not feel that any further regulation is required or necessary either for efficacy or safety. The orthopaedic literature is replete with the value of allograft. I feel that further regulation may curtail such supplies which we rely on for treating our patients and would place an un-necessary burden on bone banks which do not have the resources or expertise to satisfy premarket requirements.

It is my firm belief that no further regulation is necessary.

Yours truly,

John P. Kostuik, M.D.
Professor of Orthopaedic/Neurosurgery
Chief, Spine Division
Interim Chairman, Department of Orthopaedics

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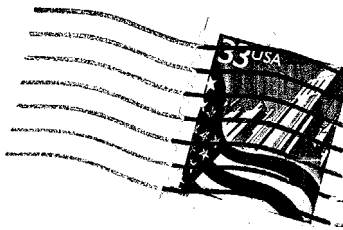

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